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January 28, 2015

Via Electronic Mail
John D. Hebert
Chief, Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Hebert.John@epa.gov

Re: Copper Development Association Submission to Clarify Points Raised in EOS/Cupron Response to Petition to Cancel Registration of Antimicrobial Cupron Enhanced EOS Surface (EPA Reg. No. 84542-7)

Dear Mr. Hebert:

The Copper Development Association (CDA) provides this submission to clarify several of the numerous factual errors and allegations contained in the Response by Cupron, Inc. (Cupron) and EOS Surfaces, LLC (EOS), dated January 8, 2015 ("the EOS/Cupron Response"). CDA urges EPA to see through the distractions raised in the EOS/Cupron Response, including mischaracterizing the Petition as "an attack on the integrity of the FIFRA registration process" in general, as "commercially motivated," and as seeking to impose "more rigorous requirements before [registration] of this one particular product." The reality is that CDA, in its role as a steward of copper-based antimicrobial products intended to protect public health, a role placed upon CDA by EPA as a requirement of registration, has raised questions about the process specific to the registration of the Antimicrobial Cupron Enhanced EOS Surface product.

These questions are particularly relevant given that the EOS/Cupron product label is an almost *verbatim* copy of the EPA-registered labels for Antimicrobial Copper Alloys (EPA Reg. Nos. 82012-1 through -6), despite the fact that EOS/Cupron did not have to address during the registration process numerous fundamental issues related to efficacy and durability that EPA

required CDA to address prior to registration. As stated in previous submissions, registration of the EOS/Cupron product should include careful consideration and proof of sustained efficacy representative of the intended uses of the material over the long term. Such performance cannot be inferred or extrapolated from the data required and submitted for solid, homogenous antimicrobial copper alloy surfaces.

This letter briefly corrects the record regarding the issues raised in the EOS/Cupron Response concerning the registration of Antimicrobial Copper Alloys, which are not the subject of the Petition at issue.

In attempting to rebut, but not directly respond to, the fundamental questions raised in the Petition, EOS/Cupron makes a number of specious claims, particularly regarding matters that EOS/Cupron allege to be equally applicable to Antimicrobial Copper Alloys. Indeed, the irony here is that these matters in fact were addressed as part of the registration for Antimicrobial Copper Alloys and demonstrate the very purpose of the Petition: namely, that the registration process for the EOS/Cupron product did not examine a multitude of fundamental issues that CDA was required to address prior to registration.

These issues include:

(1) *The Effects of Wear and Oxidation/Discoloration*: Long-term efficacy of EOS/Cupron is unproven (due to depletion of copper oxide particles or otherwise) and was not addressed in the registration process, as detailed in the Petition. EOS/Cupron allege that similar arguments could be raised for Antimicrobial Copper Alloys due to the effects of discoloration and oxidation.[1] This is an excellent point and one that in fact was addressed in depth by CDA and EPA during the registration of Antimicrobial Copper Alloys, which included examination and testing of oxidized and decades-old copper alloys. No similar examination was conducted for the EOS/Cupron product.

(2) *Long-term Durability and Efficacy*: EOS/Cupron contend that the need for long-term efficacy data also should subject Antimicrobial Copper Alloys to cancellation or suspension.[2] In fact, EPA examined information related to the long-term performance, including chemical and physical stability and durability, of copper alloys, which are required to meet detailed ASTM specifications over the product life. In doing so, it was recognized that copper alloys remain chemically and physically consistent over the expected useful life of the product (which is decades long). No such specifications or long-term experience of use exist for the EOS/Cupron product, and the efficacy testing that was conducted for the EOS/Cupron product cannot be used to presume similar performance over the

[1] EOS/Cupron Response at 7.

[2] EOS/Cupron Response at 8.

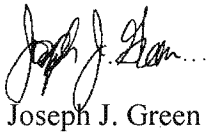
life of a product that may change physically and chemically over time due to numerous factors raised in the Petition.

(3) *Testing of Different Shapes*: EOS/Cupron contend that the efficacy of their product is not altered when the material is shaped into different forms, and contend that if efficacy testing were required for different forms of their product, then such testing also should be required for copper alloys. Again, EOS/Cupron miss the fundamental point that these issues were addressed during the registration process for Antimicrobial Copper Alloys, which are produced to maintain the same chemical and physical characteristics throughout production and for the intended end use form of the product, as required by ASTM specifications and demonstrated by a long history of human experience using copper alloys. These questions should have been examined in the EOS/Cupron registration process as well.

Each of these issues were addressed by CDA to EPA's satisfaction prior to registration of Antimicrobial Copper Alloys. The failure to address these and other issues in registering the EOS/Cupron product is the basis for the Petition at issue.

CDA appreciates the opportunity to correct the record and would be happy to provide further information or meet with EPA to discuss the registration and history of Antimicrobial Copper Alloys. In reviewing these issues, it is clear that EOS/Cupron was not required during the registration process to address important use-specific efficacy matters that were fundamental to the registration of Antimicrobial Copper Alloys, and are likewise fundamental to the protection of public health in the use of antimicrobial environmental touch surfaces. Thank you for your continued consideration of the Petition.

Respectfully,



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cc: Jennifer McLain, Acting Director, Antimicrobials Division (Mclain.Jennifer@epa.gov)
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